May 20, 2004

Sarah Loftus McLallen
Manager, CHEMSTAR
American Chemistry Council
Petroleum Additives Health Environment and
Regulatory Task Group (HERTG)
1300 Wilson Boulevard
Arlington, VA 22209

Dear Ms. McLallen:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Methylcyclopentadienyl Manganese Tricarbonyl posted on the ChemRTK HPV Challenge Program Web site on January 14, 2004. I commend the American Chemistry Council Petroleum Additives Health Environment and Regulatory Task Group (HERTG) for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that the American Chemistry Council Petroleum Additives Health Environment and Regulatory Task Group (HERTG) advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-*S*-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
Methylcyclopentadienyl Manganese Tricarbonyl (MMT)

Summary of EPA Comments

The sponsor, the American Chemistry Council Petroleum Additives Panel Health, Environmental, and Regulatory Task Group (HERTG), submitted a test plan and robust summaries to EPA for Methylcyclopentadienyl Manganese Tricarbonyl (MMT) (CAS No. 12108-13-3), dated December 10, 2003. EPA posted the submission on the ChemRTK HPV Challenge Web site on January 14, 2004.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties. The submitter needs to provide measured melting point data for MMT. The submitter needs to indicate in its robust summaries whether the boiling point and vapor pressure data are measured or calculated.

2. Environmental Fate. EPA recommends the use of the EQC Level III fugacity model rather than EQC Level l fugacity model to estimate transport and distribution.

3. Health Effects. The submitted data are adequate for all health effects endpoints for the purposes of the HPV Challenge Program.

4. Ecological Effects. The submitted data for invertebrates are adequate for the purposes of the HPV Challenge Program. EPA agrees with the submitter's testing proposal for acute toxicity to fish and algae.

EPA Comments on Methylcyclopentadienyl Manganese Tricarbonyl

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility).

The data provided by the submitter for partition coefficient and water solubility are adequate for the purposes of the HPV Challenge Program. The data provided for boiling point and vapor pressure are adequate only if the submitted data are measured rather than calculated.

Melting point. The submitter indicates in its test plan that melting point is not applicable because MMT is a liquid. EPA disagrees. For the purposes of the HPV Challenge Program, the submitter needs to provide measured melting point data for MMT following OECD guidelines. For values under 0 °C, calculated values are adequate for the purposes of the HPV Challenge Program.

Boiling point. The submitter needs to indicate in its robust summaries whether the submitted boiling point data are measured or calculated. If calculated, the submitter needs to provide measured data following OECD guidelines. For values >300 °C, calculated values are adequate for the purposes of the HPV Challenge Program.

Vapor pressure. The submitter needs to indicate in its robust summaries whether the submitted vapor pressure data are measured or calculated. If calculated, the submitter needs to provide measured data following OECD guidelines. Calculated values $>10^{-5}$ Pa are not adequate for the purposes of the HPV Challenge Program.

Environmental Fate (photodegradation, stability in water, biodegradation, transport and distribution (fugacity).

The data provided by the submitter for photodegradation and biodegradation are adequate for the purposes of the HPV Challenge Program.

Stability in water. The submitter did not provide hydrolysis data, but stated in the test plan that the potential for MMT to hydrolyze will be characterized in a technical discussion. EPA agrees with this approach. However, EPA located information in the same study the submitter used for water solubility and partition coefficient stating that the "minimum hydrolysis half-life, therefore is 500 days" (Garrison A. et al. 1995. Environmental Fate of Methylcyclopentadienyl Manganese Tricarbonyl, Environmental Toxicology and Chemistry, Vol 14, No. 11, pp 1859-1864). EPA recommends that the submitter include this information in its technical discussion.

Transport and Distribution (fugacity). The submitter did not provide fugacity estimates, but stated that the "relative distribution of MMT among environmental compartments will be evaluated using EQC Level I fugacity modeling." EPA disagrees with this approach. Although EPA had previously recommended the use of EQC Level I, this model is somewhat limited. EPA believes that values based on a level III fugacity model are more realistic and useful for estimating a chemical's fate in the environment. When developing the fugacity estimations, the submitter needs to use as much measured data as possible. The use of estimated values introduces uncertainties that then become magnified in modeling applications.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

The submitted data are adequate for the purposes of the HPV Challenge Program.

Ecological Effects (fish, invertebrates, and algae).

Fish. The submitter proposed testing for acute toxicity to fish and algae in the Summary of Available Data on page 6 of the Test Plan and in the Summary Table on page 9 of the Test Plan, but stated in the Data Assessment and Test Plan for Acute Aquatic Ecotoxicity on pp. 6-7 that acute aquatic toxicity data in fish are adequate. It is assumed that this last statement by the submitter is an error because no acute toxicity data for fish were submitted.

Specific Comments on the Robust Summaries

Health Effects

General. Most of the studies submitted pre-date Good laboratory Practices (GLP) because they were performed prior to 1979. However, if available, it would be useful to know the purity of the test substance in the robust summaries submitted. This may help explain variations observed in the study results, especially for the acute toxicity data.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.